DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Alan J. Landauer, President & CEO
Landauer Hospital Supplies, Inc.
18 Sargent Place
Mount Vernon, NY 10550

March 6, 2000

Ref: NYK-2000-42

Dear Mr. Landauer:

During an inspection of your medical oxygen filling facility located in Mount Vernon, New York conducted on January 26 through February 7, 2000, our investigator documented deviations from the Current Good Manufacturing Practice for Finished Pharmaceuticals Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your oxygen drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to, the following:

1. Failure to establish written procedures for the calibration of, and to properly calibrate, the oxygen analyzer used for the assay of oxygen, USP as required by 21 CFR 211.160(b)(4). For example, your firm did not calibrate the [redacted] oxygen analyzer according to the manufacturer's directions, including the use of a certified cylinder of nitrogen gas to adjust the "zero" on the meter and a certified cylinder of oxygen gas to adjust the "span" on the meter.

2. Failure to establish written procedures for handling all complaints about a drug product and to adequately investigate complaints and document the findings of an investigation and follow-up as required by 21 CFR 211.198. For example, on January 19, 2000, your firm received a complaint about the delivery of a reportedly empty oxygen tank to a patient. There was no written record of your firm's investigation of the incident including your conclusions and follow-up.

3. Failure to establish the reliability of your supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals as required by 21 CFR 211.84(d)(2). For example, your firm receives a certificate of analysis for each lot of bulk liquid oxygen, USP received from your supplier. However, there was no record of your firm periodically verifying the reliability of the supplier's analyses as required by your firm's own policies and procedures.

4. Failure to document that each employee engaged in the manufacture, filling, processing, holding, or shipping of your oxygen drug products is trained in the particular operations that the employee performs and in current good manufacturing practice as it relates to the employee's functions as required by 21 CFR 211.25.

Neither the above identification of CGMP violations nor the inspectional observations (a copy of the Form FDA 483 is enclosed) presented to you at the conclusion of the inspection is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drug products so that they may take this information into account when considering the award of contracts. Additionally, by copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to, seizure and injunction.

You should notify this office in writing, within 15 working days after receipt of this letter, of (1) each step that has been or will be taken to completely correct the current violations and to prevent the recurrence of similar violations; (2) the time within which the corrections will be completed; (3) any reason why the corrections have not been completed within the response time; and (4) any documentation necessary to show the corrections have been achieved.

Your reply should be sent to the attention of Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Tel. (718) 340-7000 ext. 5582.

Sincerely,

Brenda J. Holman
District Director

Enclosures: Form FDA 483 dated February 7, 2000